

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

**EXPERT REPORT OF NATHANIEL M. SIMS
REGARDING NON-INFRINGEMENT**

I, Nathaniel M. Sims, submit this expert report on behalf of Radianse, Inc. the Defendant in the above-cited litigation (“Radianse”).

GENERAL BACKGROUND AND QUALIFICATIONS

1. My name is Nathaniel M. Sims, and I have been retained by Radianse as a technical expert in connection with the above-cited litigation. I am currently an Assistant Professor of Anesthesia at Harvard Medical School, as well as a Physician Advisor to the Department of Biomedical Engineering of Massachusetts General Hospital, a part of Partners Healthcare System, Inc. In my role as a Physician Advisor, I am involved in the development and management of biomedical devices with a specific focus on technology development and implementation in the field of patient safety, medical error reduction, and workforce productivity and satisfaction. I also operate a research and development laboratory that is principally funded from distributions of patent licensing royalty income received by MGH for inventions created in the laboratory in collaboration with others.

2. My qualifications are recited on the attached curriculum vitae, marked as Exhibit A. A list of patents I was involved in the development of is attached as Exhibit B. Over the years my ‘non-clinical’ technology development activities, both self-directed and institutionally-directed, have resulted in broad awareness on my part of technology trends in my interest areas, and a host of close collaborations with academic and industrial engineers. In other areas of activity, I have been for several years a “Focus Area Leader” for CIMIT (Center for the Integration of Medicine and Innovative Technology), a Boston-based non-profit consortium of hospitals, universities, and industry working on challenging medical innovation problems. Three projects in which I have been intensely involved include the ‘MGH/CIMIT Operating Room of the Future’, the Department of Defense funded “Warrier Life Signs Detection System” (an R&D effort in the area of wearable physiological monitoring and health state assessment systems), and the “MGH/CIMIT Ambulatory Practice of the Future.” See www.cimit.org/utmon.html. Participation in these activities has broadened and extended the collaborations and broad technology awareness that have resulted from the operations of my research and development laboratory.

3. I earned a Bachelor of Arts from Harvard College. I earned a Medical Doctorate from Columbia University College of Physicians and Surgeon. I am a Board-Certified Physician.

4. In 1989, Mr. James P. Welch and I were asked by Massachusetts General Hospital (MGH) to design and implement an affordable, ‘flexible’ multi-parameter vital signs monitoring system to address the growing problem of higher-acuity (i.e., more-ill) patients needing to be housed and cared for in the ‘general care’ areas of our hospital. MGH’s goal was to affordably

extend the availability of 'high tech' patient care devices, such as physiological monitoring systems and drug infusion pumps, from their prior concentration in the Intensive Care Units and Operating Room areas of the Hospital, to more distributed patient care areas. To accomplish this objective by purchasing the typical, then-available technologies (fixed-in-position) in patient care area 'bedsides' would have been impractical (excessively complex). It also would have been prohibitively expensive, because of the need to scale-up the solution to hospitals with several million square feet of clinical real estate and many hundreds of patient rooms.

Additional challenges included the need to address the goal of continuously monitoring mobile patients where there is a low patient-to-caregiver ratio, coupled with the need for caregivers to rapidly locate the patients in case of physiological collapse detected by the vital signs monitoring system. Accordingly, during the period 1989-1992, we conceived, designed, reduced to practice, patented, licensed, obtained FDA 510(k) approval to market, implemented under human studies investigations, and then supported the marketing of a "Flexible Monitoring" system. The "Flexible Monitoring" system is a "network of portable patient monitoring devices" comprising a pool of rugged multi-parameter vital signs monitors. It also comprises a computer network having a specific topology, with the terminal portions of the network disposed in specific locations. For ambulatory patients equipped with wearable wireless vital signs monitors, a 'microcellular' array of wireless access points disposed in known locations was provided. The technology was thus designed and patented. The result includes U.S. Patent Number 5,319,363. The technology was also licensed to a medical device manufacturer (Protocol Systems, Inc. of Beaverton, OR, now WelchAllynMonitoring), received FDA 510(k) approval to market during

approximately 1991 with product being first sold commercially during early 1992 and still sold worldwide to this day.

5. I have known and worked with Mr. Dempsey and the principals of Radianse, Inc. intermittently over 15 years regarding engineering and clinical issues where we found ourselves working in the same area of interest, principally networked hospital patient physiological monitoring systems, wireless data networks, and indoor locating and positioning systems. I have served as a research principal investigator in a CIMIT-funded project for the Operating Room of the Future in which Radianse first deployed its Indoor Location System.

6. I have no business, financial, or equity interest in Radianse, Inc.

7. In relation to Versus and Precision Tracking FM, Inc., a review of my records indicate that, in November 1991, I intensified a prior interest in "Auto-ID" or automatic identification technology, in part by attending a conference called "Scan-Tech" in Dallas Texas. At that conference, I received promotional materials and met employees of Precision Tracking FM and Dallas Semiconductor, each then displaying technology solutions potentially relevant to the problem of locating mobile devices and assets (such as portable patient care devices) in indoor locations. My principal contacts included Michael L. Bolan and Stephen M. Curry at Dallas Semiconductor and Douglas Hellie at Precision Tracking FM.

8. I have no business, financial, or equity interest in Versus.

9. I am being compensated for my services as an expert witness on a retainer basis.

MATERIALS RELIED UPON

10. In forming my opinion, I have reviewed the following materials:

- a) US Patents as referenced in Exhibit C of this report, including patent numbers 5,027,314 issued to Linwood et al. ("314 patent"); RE 36,791 issued to Heller ("791 patent"); 5,572,195 issued to Heller ("195 patent"); and 6,154,139 issued to Heller ("139 patent").
- b) Portions of the file history of the prosecution before the US Patent and Trademark Office that lead to the issuance of one or more of US Patent Numbers 5,027,314; RE 36,791; 5,119,104 (The parent of RE36,791), 5,572,195 and 6,154,139.
- c) Radianse's proposed claim construction attached as Exhibit D.
- d) Technical Documentation and Specifications for Radianse's system in suit.
- e) The Affidavit of Paul Tessier in Support of Radianse's Consolidated Motion to Dismiss for Lack of Standing.
- f) The Report of Expected Testimony of Walter S. Leipold Pursuant to Federal Rule of Civil Procedure 26(a)(2)(B)
- g) Portion of the transcript of the deposition of Alan C. Heller.
- h) My own research on the subject matter of the patents in suit. An example of the research can be seen in Exhibit E

11. In preparing this report, I have discussed the operation and implementation of Radianse's system with Michael Dempsey and Paul Tessier.

13. Moreover, in my role as Physician Advisor, I have a basic understanding of how Radianse's system operates and I have seen it operate in its intended environment.

12. In addition, I expect to consider and render opinions on other documents and evidence which have not yet been supplied by Radianse or Versus, or experts retained by same, pleadings, testimony, affidavits, expert reports, demonstrative evidence, and arguments offered by parties in this matter. In light of information gathered from such material, I may supplement, and/or amend this report and these materials may also bear on any rebuttal report that I may provide.

SUMMARY OF EXPECTED TESTIMONY AND OPINIONS

14. I expect to testify at least about how Radianse's system does not infringe claims 1 and 9 of U.S. Patent Number 5,027,314; claims 25, 48, and 66 of U.S. Patent Number RE 36,791; claims 1, 13, and 18 of U.S. Patent Number 5,572,195; and claims 1 and 5 of U.S. Patent Number 6,154,139. I may also testify about other claims related to one or more of the patents.

15. I expect to rebut the testimony of Walter S. Leipold regarding any assertions of infringement of the '314, '791, '195, and '314 patents by Radianse's system

Non-Infringement of U.S. Patent No. 5,027,314

16. U.S. Patent Number 5,027,314 issued on June 25, 1991. The '314 patent is a continuation of Patent Application Serial Number 194,199, filed May 16, 1988, which is a continuation-in-part of Patent Application Serial Number 169,285, filed March 17, 1988.

17. Versus has asserted that Radianse's system infringes claims 1 and 9 of the '314 patent.

18. I have reviewed Radianse's proposed construction of the claim language of claims 1 and 9 of the '314 patent set forth in Exhibit D and agree with the claim construction.

19. Based on Radianse's proposed claim construction set forth in Exhibit D and my understanding of Radianse's system, Radianse's system does not infringe claims 1 and 9 of the '314 patent.

20. Claims 1 and 9 of the '314 patent require the transmitters to transmit *a light based signal representative of an identifying code unique to that transmitter.*

21. The Radianse system does not generate a light based signal that includes a unique identifying code. Radianse uses transmitters that transmit an RF signal that includes a unique identifying code that gates an IR signal. The IR signal does not have a unique identifying code.

22. Claims 1 and 9 of the '314 patent requires a number of receivers, *at least one of the receivers is associated with each of the recited areas.*

23. Radianse's system does not deploy its receivers such that one receiver is associated with each area.

24. Claims 1 and 9 of the '314 patent require a validation circuit or validating *to determine whether said electrical signals are representative of the unique identifying codes associated with said transmitters.*

25. Radianse's system does not employ a validation circuit or perform validation to determine if the received signal is representative of a unique identification code.

26. Claims 1 and 9 of the '314 patent require *scanning the receivers and accumulating with respect to each transmitter those areas in which receivers have determined that an electrical signal is representative of the unique identifying code associated with a particular transmitter.*

27. The Radianse system does not scan receivers. Rather, the Radianse system pushes information so that the processor need not monitor the receiver. The Radianse system does not accumulate the area history of each transmitter.

28. Claims 1 and 9 of the '314 patent require *accumulating a badge count for each accumulated area, where the badge count is representative of the number of times a receiver has determined that an electrical signal is representative of the unique identifying code associated with the particular transmitter.*

29. Radianse's system does not accumulate a badge count for each accumulated area.

30. For these reasons, it is my expert opinion that Radianse's system does not infringe claims 1 and 9 of the '314 patent.

Non-Infringement of U.S. Patent No. RE 36,791

31. U.S. Patent Number RE 36,791 reissued on July 25, 2000. The '791 patent is a reissue of U.S. Patent Number 5,119,104 filed on May 4, 1990.

32. Versus has asserted that Radianse's system infringes claims 25, 48, and 66 of the '791 patent.

33. As I have stated in my previous Report, I believe the '791 patent to be invalid for the reasons set forth in that report and as such Radianse's system cannot infringe the '791 patent.

34. I have also reviewed Radianse's proposed construction of the claim language of claims 25, 48, and 66 of the '791 patent set forth in Exhibit D and agree with the claim construction.

35. Based on Radianse's proposed claim construction set forth in Exhibit D and my understanding of Radianse's system, Radianse's system does not infringe claims 25, 48, and 66 of the '791 patent.

36. Claims 25, 48, and 66 of the '791 patent require receivers that receive transmissions *from an assigned area of a predetermined size.*

37. The Radianse system does not use receivers that receive transmissions from assigned areas of a predetermined size. Radianse's system does not distribute receivers in this fashion. The prosecution history and the specification of the '791 patent (and the parent '104 patent) indicate that this claim element is limited to a transmitter/receiver arrangement where there is a 1 to 1 ratio, such that only a single receiver is specifically positioned to receive only the signal from a single transmitter. The Specification at Col. 11, lines 9-48 clearly indicates that the claims are limited to an arrangement where a single receiver in an assigned area is designed to receive a signal from a single transmitter. Further support for this position is gleaned from the prosecution of the parent '104 patent. In the Response dated February 1, 1991, it was argued that the receivers only receive signals from transmitters located within an assigned area. In this same Response, on page 9, it was also argued that the claims distinguish from the cited art because "all of the references assume that radiolocation signals transmitted from an object will be received by more than one receiver." This and other statements mandate that the claims be limited to a 1 transmitter 1 receiver arrangement.

38. Claims 25, 48 and 66 of the '791 patent require that *each receiver include a data communications controller responsive to the receipt of a TAG transmission for providing a corresponding area-detection packet that includes the received TAG ID.*

39. Radianse's system does not use receivers that include a data communications controller responsive to the receipt of a tag transmission. Rather, Radianse's receivers send Ethernet packets at regular timed intervals. Radianse's system does not use corresponding area-detection packets.

40. For these reasons, it is my expert opinion that Radianse's system does not infringe claims 25, 48, and 66 of the '791 patent.

Non-Infringement of U.S. Patent No. 5,572,195

41. U.S. Patent Number 5,572,195 issued on November 5, 1996. The '195 patent was filed with the U.S. Patent Office on August 1, 1994.

42. Versus has asserted that Radianse's system infringes claims 1, 13, and 18 of the '195 patent.

43. As I have stated in my previous Report, I believe the '195 patent to be invalid for the reasons set forth in that report and as such Radianse's system cannot infringe the '195 patent.

44. I have also reviewed Radianse's proposed construction of the claim language of claims 1, 13, and 18 of the '195 patent set forth in Exhibit D and agree with the claim construction.

45. Based on Radianse's proposed claim construction set forth in Exhibit D and my understanding of Radianse's system, Radianse's system does not infringe claims 1, 13, and 18 of the '195 patent.

46. Claims 1, 13 and 18 of the '195 patent requires *infrared transmitters that transmit identifying codes*.

47. Radianse's system does not use infrared transmitters that transmit identifying codes.

48. Claims 1, 13, and 18 of the '195 patent requires a *variable-based protocol that implements object identifier variables*.

49. Radianse's system does not employ a variable-based protocol that implements object identifier variables. Radianse's system utilizes a fixed communication protocol.

50. Claims 13 and 18 of the '195 patent requires a plurality of *infrared sensors* for receiving transmitted *unique identifying codes* from infrared transmitters.

51. Radianse's system does not use infrared transmitters that transmit identifying codes. Since Radianse's system does not transmit unique identifying codes, the infrared sensors do not receive unique identifying codes from infrared transmitters.

52. Claim 18 of the '195 patent requires sending a message from the computer to the *external device controller*, the message containing *an identification of a channel of the external device controller* instructing the external device controller *to activate the channel*.

53. Radianse's system does not employ an external device controller, and thus does not have a channel to activate or communicate with.

54. Claim 18 of the '195 patent requires *said message sent in response to said unique identifying code* provided by the interface circuitry to the computer network.

55. Radianse's system does not employ IR transmitters that generate a signal having a unique identifying code. As such, Radiance's receivers do not send a message in response to receiving a unique identifying code.

56. Claim 18 of the '195 patent requires *activating in the external device controller the channel identified in said sending a message step in response to receiving said message sent by the computer.*

57. As state above, Radianse's system does not employ an external device controller, and thus does not have a channel to activate.

58. For these reasons, it is my expert opinion that Radianse's system does not infringe claims 1, 13, and 18 of the '195 patent.

Non-Infringement of U.S. Patent No. 6,154,139

59. U.S. Patent Number 6,154,139 issued on November 28, 2000. The '139 patent was filed with the U.S. Patent Office on April 21, 1998.

60. Versus has asserted that Radianse's system infringes claims 1 and 5 of the '139 patent.

61. I have reviewed Radianse's proposed construction of the claim language of claims 1 and 5 of the '139 patent set forth in Exhibit D and agree with the claim construction.

62. Based on Radianse's proposed claim construction set forth in Exhibit D and my understanding of Radianse's system, Radianse's system does not infringe claims 1 and 5 of the '139 patent.

63. Claims 1 and 5 of the '139 patent require transmitting a substantially line-of-sight signal (e.g., an IR signal) that includes a *unique TAG ID*.

64. Radianse's system does not use IR transmitters that have a unique ID or identification code.

65. Claims 1 and 5 of the '139 patent require an array of receivers distributed within the tracking environment, wherein the array of receivers includes an *extended area receiver* for receiving a plurality of substantially non-line-of-sight signals and a plurality of *limited area receivers*, each of the limited area receivers receiving substantially line-of-sight signals.

66. Radianse does not use separate line-of-sight (IR-only) receivers and non line-of-sight (RF-only) receivers. The Radianse design employs a single receiver that is adapted to receive both RF and IR signals. Radianse does not use the concept of an extended area receiver.

67. Claims 1 and 5 of the '139 patent require generating an *extended area detection packet* including the *unique TAG ID* in response to each received non-line-of-sight signal.

68. Radianse's system does not use an extended area receiver and does not generate an extended area detection packet. Radianse does not generate any packet in response to the receipt of a non-line-of-sight signal.

69. Claims 1 and 5 of the '139 patent require generating a *limited area detection packet* including the *unique TAG ID* in response to each received line-of-sight signal.

70. Radianse's system does not transmit or receive line-of-sight signals including the unique tag id. Radianse's system does not use a limited area receiver and does not generate a limited area detection packet. Radianse's system does not generate separate line-of-sight and non-line-of-sight packets.

71. Claims 1 and 5 of the '139 patent require determining the location of each TAG and its associated subject based on the *identity of the extended area and limited area receivers* for the TAG as represented by its *extended area and limited area detection packets*.

72. As discussed above, Radianse's system does not use extended area and limited area receivers. Radianse's system also does not use extended area and limited area detection packets.

73. Claim 5 of the '139 patent requires a *data communications controller*.

74. Radianse's system does not employ a controller to collect information packets. Radianse's receivers connect directly to a computer network.

75. For these reasons, it is my expert opinion that Radianse's system does not infringe claims 1 and 5 of the '139 patent.

Rebuttal of Expected Testimony of Walter S. Leipold

76. I have reviewed the Report of Expected Testimony of Walter S. Leipold.

77. In my reading of Mr. Leipold's report, Mr. Leipold does *not* dispute the operation of Radianse's system, namely, that Radianse's system uses transmitters that transmit an *RF signal* that includes a unique identifying code that gates a non-identifying IR pulse pattern sent by the transmitter. Mr. Leipold confirms that Radianse's system does not employ IR transmitters that transmit a unique ID.

78. In his report, Mr. Leipold does make some statements that require further comment.

79. Mr. Leipold contends that since it is possible to refer to Radianse's RF and IR signals together as one transmission, then that one transmission can be considered "a light based signal."

80. This is a confounding jump in logic. While, in strained construction, Radianse's IR and RF signals together can be referred to as one transmission, such a transmission can have

multiple parts, wherein each part may be different from the other. A transmission can have sequences of signals, wherein each signal in the sequence may be different. In the case of the Radianse system, there is an RF signal and an IR signal. The proper construction of the claimed phrase “a light based signal” refers to a signal transmitted by infrared radiation. If Radianse’s RF and IR signals are one transmission, there is no way this could be “a light based signal” because the transmission involves both an IR signal and an RF signal.

81. Mr. Leipold also argues that the claims of the ‘139 and ‘314 patents do not require that the unique tags must be transmitted in the form of infrared radiation.

82. Mr. Leipold’s argument is inconsistent with the plain language of the claims. In particular, claim 1 of the ‘314 patent recites “...each of said transmitters comprising transmission means for transmitting a *light based signal representative of an identifying code unique to that transmitter....*” The proper construction of the claimed phrase “a light based signal” refers to a signal transmitted by means of infrared radiation. Likewise, claim 1 of the ‘139 patent recites “...providing a TAG capable of transmitting a *substantially line-of-sight signal* including a unique TAG ID substantially simultaneously with a substantially non-line-of-sight signal also including the unique TAG ID....” The proper construction of the phrase a “substantially line of sight signal” is a signal such as an infrared signal or a visual light wave signal that will not travel through common building materials that are used to form a room in a building (wood, plaster, drywall, etc.).

83. Mr. Leipold argues that “[b]ecause of its required timing association with an RF signal, the IR signal in the Radianse architecture allows a tag’s ID to be identified.”

84. Mr. Leipold's assessment of the Radianse system is incorrect and misstates the facts. The Radianse tag does not send a unique tag ID via IR (nor any other substantially line-of-sight signal). All Radianse tags send an identical IR pulse train. This signal, by its very nature, is a non-unique signal and would not serve to identify the IR transmitter. The IR signal is gated by a RF transmission using a patent pending technique. The Radianse External Specification states that "five IR pulses are sent with the spacing between trailing edges increasing by 300uS each time." Comments in the source code for the Tag state that "the IR transmission is a series of carrier pulses. It is intended that the timing of these pulses be used to detect that a valid signature has been received."

85. Mr. Leipold argues that "because the IR signal must be associated with the RF signal to give it meaning, the Radianse transmission scheme incorporates an IR signal that 'includes' or is 'representative of' a unique tag ID.

86. This is simply not true. If a receiver receives an IR signal without an RF signal, the IR signal does not include or represent a unique ID, because the receiver has no idea which transmitter the IR signal came from (i.e., the IR signal could have come from any number of transmitters). As such the IR signal would actually be representative of a several transmitters and is therefore not at all unique.

87. Mr. Leipold argues that an e-mail to a customer from Steve Schiefen which states that Radianse technicians will sometimes "'tune' the receivers down to decrease receiver detection radius," suggests that Radianse attempts to achieve non-overlapping reception ranges.

88. Radianse's Receivers always receive signals from Tags at the maximum possible distance. Nothing is done to the RF receivers, antennas or tags to change the distance that the RF

is received. The term "tune" refers to setting a received signal strength value (RSSI) that indicates the boundary of a space (most typically a wall of a room). The system then acts on the data differently, but the reception range is not changed. It is my understanding that when Mr. Schiefen refers to "tuning" the Receivers to decrease the radius, he is referring to the RSSI value and not some actual change in reception.

89. Mr. Leipold states "[i]n my opinion, the act of associating an area with a receiver via the Map Tool, adjusting the sensitivity of a receiver, or selecting the placement of a receiver to control the area monitored constitutes 'each receiver being configured to receive TAG transmissions from an assigned area of predetermined size.'"

90. Radianse does not configure its Receivers to receive transmissions from an assigned area. The Radianse Receivers have a coverage area of approximately thirty-feet and have overlapping areas of coverage. Radianse employs an algorithm that utilizes received signal strength (RSSI), changes in RSSI, the presence or absence of an IR gating signal, previous location history, and previous signal strength to determine location. The Radianse External Specification states that Receivers have a "RF range >/= 10m (32.8 ft.)"

91. Mr. Leipold makes the assumption that "object identifier variable" refers to "the representation within the system of a tracked object's ID."

92. In review of the '195 patent and my research on the topic (see Exhibit E) it appears "object identifier variables" are used to receive stimuli or status information from devices and to send control instructions or requests to devices. The server maintains a management information base that defines a set of conceptual variables that are maintained for devices on the network. These conceptual variables can be actual variables or parameters

generated by performing functions. Clients can get or set variables over the network using object identifiers. A "get" command could ask for the status of a particular device and the device would respond by saying its status is XXXXX. Both the "get" command and response use object identifier variables to let the other device know what is being requested or transmitted. Radianse's system does not use this type of transmission. Radianse's system sends all the available information from a device with each transmission from that device. No object identifiers are required since the sequence is always the same and the data elements are always the same length. While the packet size in Radianse's system can vary since Receivers can hear from a different number of tags in a given period of time, the data from each tag is fixed in sequence and length.

93. Mr. Leipold asserts that the phrase "variable-based protocol" has no particular technical meaning and, thus, assumes that the phrase "describes any protocol which conveys variables, including protocols that convey the values of object identifier variables."

94. From reading the '195 patent it is clear that SNMP is an example of what is meant by the phrase "variable-based protocol." It is my understanding that Radianse does not use SNMP or anything like SNMP. In view of this example and my research on the topic (see Exhibit E), one way to describe a variable based protocol that implements object identifier variables is to say that since not all the data for a device is requested or sent in each transmission, the specific data being requested or sent must be identified; otherwise the receiving device does not know what sub-segment of data is being requested or sent. Simply put, a variable based protocol that implements object identifier variables is a protocol where the "name" (identifier) of the data is included with the transmission of the data. As discussed above, Radianse's system does not use this type of transmission. Radianse's system sends all the available information from a

device with each transmission from that device. No object identifiers are required since the sequence is always the same and the data elements are always the same length.

95. Mr. Leipold asserts that the use of the term "response" in the '139 patent is not meant to mean "immediate response."

96. In fact, in the deposition of Alan C. Heller, Mr. Heller, the inventor of the '139 patent, states that "immediate response" was what indeed was intended by the term "responsive."

Nathaniel M. Sims, MD
Nathaniel M. Sims, MD

Dated: October 28, 2005

CERTIFICATE OF SERVICE

I, Karen E. Keller, Esquire, hereby certify that on December 2, 2005, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that copies of the foregoing document were served by hand delivery on the above-listed counsel of record.

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